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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/809,965

03/25/2004

Dave S.B. Hoon

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

09/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,965	Applicant(s) HOON ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-13,15-18,20,21,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7-13,15-18,20,21,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Applicants' response to the office action filed on June 06, 2008 has been considered and acknowledged.

Status of the application

2. Currently claims 1-2, 4-5, 7-13, 15-18, 20-21, 23-24 are pending. Claims 3, 6, 14, 19, 22, and 25-31 were cancelled. Claims 17-18, 20, 23 were amended. Applicants' arguments and the amendment have been fully considered and deemed persuasive for the reasons that follow.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 1-2, 5, 7-13, 16-18, 20-21, 23-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Klein et al. (US 6,673,541).

Klein et al. teach a method of claim 1-2, 5, 7, 9, 11, 13, 16-18, 20, 23, detecting DNA markers in sample or detecting a cancer comprising:

providing a cell-free bone marrow sample from a subject (see col. 6, line 32-40, col. 16, line 45-67, col. 17, line 1-18);

detecting one or more DNA markers in the sample, wherein the DNA markers are indicative of LOH or hypermethylation (see col. 12, line 18-48, col. 17, line 3-18).

With regard to claim 2, Klein et al. teach that the DNA markers are from 8p (see col. 17, line 14-18).

With regard to claim 5, Klein et al. teach that said DNA markers include APC (see col. 12, line 38-48).

With regard to claims 8, 10, 12, 21, 24, Klein et al. teach that said cancer is breast cancer (see col.17, line 3-18).

With regard to claims 17-18, 20, 23, Klein et al. teach detecting a combination of LOH and hypermethylation of markers indicative of cancer (see col. 12, line 38-48, col. 17, line 3-18).

Accordingly Klein et al. anticipates the instant claims.

B. Claims 1-2, 5, 7-13, 16-18, 20-21, 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Klein et al. (WO 00/017390). (WO 00/017390 is herein refers to US 6,673,541 and the rejection based on the WO 00/017390 is represented by US 6,673,541).

Klein et al. teach a method of claim 1-2, 5, 7, 9, 11, 13, 16-18, 20, 23, detecting DNA markers in sample or detecting a cancer comprising:

providing a cell-free bone marrow sample from a subject (see col. 6, line 32-40, col. 16, line 45-67, col. 17, line 1-18);

detecting one or more DNA markers in the sample, wherein the DNA markers are indicative of LOH or hypermethylation (see col. 12, line 18-48, col. 17, line 3-18).

With regard to claim 2, Klein et al. teach that the DNA markers are from 8p (see col. 17, line 14-18).

With regard to claim 5, Klein et al. teach that said DNA markers include APC (see col. 12, line 38-48).

With regard to claims 8, 10, 12, 21, 24, Klein et al. teach that said cancer is breast cancer (see col.17, line 3-18).

With regard to claims 17-18, 20, 23, Klein et al. teach detecting a combination of LOH and hypermethylation of markers indicative of cancer (see col. 12, line 38-48, col. 17, line 3-18).

Accordingly Klein et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 4, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (US 6,673,541) in view of Silva et al. (Annals of Surgical Oncology, Vol. 9(1), pp. 71-76, 2002).

Klein et al. teach a method of detecting DNA markers in cell-free bone marrow cells as discussed above in section 3A.

However Klein et al. did not teach DNA markers as claimed in claim 4 and 15.

Silva et al. teach a method of detecting DNA markers in plasma samples, wherein the DNA markers are selected from D17S855, D17S654, D16S421, D10S197, mutation in p53 gene and hypermethylation marker p16 (see page 71, abstract, page 72, col. 2, paragraph 2, page 73, col. 1, paragraph 1-2).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for detecting DNA markers in cancer samples as taught by Klein et al. with the DNA markers as taught by Silva et al. for the purpose of developing a sensitive method for detecting a cancer. An ordinary person skilled in the art would have a reasonable expectation of success that the combination of the method of Klein et al. and the DNA markers of Silva et al. would result in a sensitive method for detecting cancer because Silva et al. explicitly taught the use of microsatellite markers in detecting cancer and the association of said markers in the prognosis of cancer (see page 71, abstract) and such modification of the method is considered as obvious over the cited prior art.

Response to arguments:

5. In view of the Applicants' arguments and amendment all the previous rejections that are not reiterated, were withdrawn herein.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637

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